

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	CIVIL ACTION: 01-CV-12257-PBS
	)	
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO	)	
THE CLASS ACTION	)	<b>[FILED UNDER SEAL]</b>

**TRACK 2 DEFENDANTS' MEMORANDUM REGARDING HAROLD BEAN,  
IN FURTHER OPPOSITION TO CLASS CERTIFICATION**

**(HIGHLY CONFIDENTIAL)**

### **PRELIMINARY STATEMENT**

Plaintiffs' struggle to find appropriate Class 1 representatives for Track 2 is both apparent and telling. As late as their Fourth Amended Master Consolidated Complaint, Plaintiffs were still trying to add claims relating to new drugs against various Track 2 Defendants – despite this Court's clear admonition not to do so. (*See generally* Docket No. 2249.) When the Court put a stop to that effort, ordering that the new *drugs* be stricken (*see* Order of 4/10/2006), Plaintiffs changed tack and began adding new *plaintiffs*. Specifically, in their motion to certify classes as against Track 2, Plaintiffs – for the first time in this years-old litigation – added Mr. Harold Bean as a proposed Class 1 representative. (*See generally* Docket No. 2582.)

Although the Court permitted Plaintiffs to amend the FAMCC to include Mr. Bean, discovery confirms that even Mr. Bean cannot salvage Plaintiffs' doomed efforts to certify Class 1 against the Track 2 Defendants. Plaintiffs have brazenly attempted to take advantage of this Court's patience, using Mr. Bean's recent addition to try to (1) advance the stricken drugs against Track 2 Defendants, and (2) add yet other new drugs to the case, some of them not even sold by any Track 2 Defendant. (*See* Supplemental Declaration of Steven J. Young In Support Of The Track 2 Defendants' Opposition To Class Certification (“Young Bean Dec.”) ¶¶ 7-10 & Ex. 10 (identifying encounters that do not involve Track 2 Subject Drugs).) This blatant end-run around this Court's orders is, of course, plainly impermissible.

Putting aside these clearly inappropriate drugs, none of the actual identified Track 2 Subject Drug encounters<sup>1</sup> supports certification of Mr. Bean as a Class 1 representative because:

---

<sup>1</sup> Mr. Bean was named as a representative for the following Track 2 Defendants: Abbott, Amgen, Baxter, Dey, Pharmacia, and Fujisawa. However, his [REDACTED] implicate only Abbott, Amgen, Baxter, Pharmacia, and Dey. A table detailing why each of these Subject Drug encounters does not fall within the definition of Class 1 is attached hereto as Exhibit 1.

- A careful review of the evidence confirms that, in fact, each of the drug encounters falls outside the definition of Class 1 – accordingly, Mr. Bean lacks standing to pursue Class 1 claims against the Track 2 Defendants.
  - For all but [REDACTED], Mr. Bean either incurred no obligation to pay anything for the drug or any payment made was not based on AWP.
  - The remaining [REDACTED]. It is not possible to determine the source of such a drug based on the reimbursement data available, and Plaintiffs have presented no evidence that either of these encounters involved a drug from a Track 2 Defendant. Moreover, because multi-source drugs are reimbursed under one single reimbursement level, it is not possible for any given source of a multi-source drug to effect higher reimbursement for its drug than for a competitor's.
- The document-intensive and time-consuming process required to assess whether each drug encounter meets the Class 1 definition continues to militate against certification of Class 1 in Track 2 – especially because of the unique issues raised by the primarily multi-source drugs at issue in Track 2.
- Finally, Mr. Bean's [REDACTED] to his claims. Under Texas law Mr. Bean must prove both reliance and causation, which further disables him from representing Class 1 because these elements are not appropriate for adjudication on a class-wide basis – as this Court has already recognized.

For these reasons, in addition to those raised in the rest of Defendants' Track 2 class certification briefing, Class 1 cannot be certified – especially with Mr. Bean as a representative.

### ARGUMENT

**I. MR. BEAN CANNOT REPRESENT CLASS 1 BECAUSE HIS CLAIMS ARE NOT TYPICAL OF CLASS 1: HE LACKS STANDING BECAUSE HE CANNOT SHOW THAT ANY OF HIS SUBJECT DRUG ENCOUNTERS FALLS WITHIN THE DEFINITION OF CLASS 1.**

The typicality requirement ensures that when a proper class representative litigates its claim against a defendant, it will necessarily advance the interests of the entire class. *Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 156 (1982); *Wooden v. Bd. of Regents of the Univ. Sys. of Ga.*, 247 F.3d 1262, 1288 (11th Cir. 2001) (“One of the core purposes of conducting typicality review is to ensure that the named plaintiffs have incentives that align with those of absent class members

so as to assure that the absentees' interests will be fairly represented.") (internal quotation marks omitted).

As this Court previously recognized, one aspect of typicality – and indeed, a threshold question for class certification – is that there must be “an individual class representative with standing to sue each defendant.” *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 80 (D. Mass. 2005); *see Miller v. Pacific Shore Funding*, 224 F. Supp. 2d 977, 996 (D. Md. 2002) (“[I]n a multi-defendant . . . class action, the named plaintiffs must establish that they have been harmed by each of the defendants” against whom they seek to represent a class.). Indeed, the Supreme Court has “repeatedly held that a class representative must be part of the class and possess the same interest and suffer the same injury as the class members.” *Falcon*, 457 U.S. at 156 (internal quotation marks omitted); *see also Sosna v. Iowa*, 419 U.S. 393, 403 (1975) (“A litigant must be a member of the class which he or she seeks to represent at the time the class action is certified by the district court.”); *Prado-Steiman v. Bush*, 221 F.3d 1266, 1279 (11th Cir. 2000) (“It should be obvious that there cannot be adequate typicality between a class and a named representative unless the named representative has individual standing to raise the legal claims of the class.”). These basic precepts doom Mr. Bean’s effort to represent Class 1.

As analyzed extensively in expert Steven J. Young’s Bean declaration, Mr. Bean is not even a member of proposed Class 1. Stripped of drugs dropped by the Court, drugs not previously or properly named against a Track 2 Defendant, and drugs named for but not made by a Track 2 Defendant, and [REDACTED] Mr. Bean asserts a mere [REDACTED] involving Track 2 Subject Drugs. (Young Bean Dec. ¶ 5 & Exs. 3g & 10.) Of these:

- [REDACTED], and thus any payments “were not based on AWP as required by the class definition.” (*Id.* ¶ 12 & Exs. 2g & 3g.)
- [REDACTED], where it was bundled with services and not separately billed. (*Id.* ¶¶ 13-15 & Exs. 2g & 3g.) Under Hospital OPPS, a Medicare beneficiary “does not pay based on AWP.” (*Id.* ¶ 13 & n.7.)
- [REDACTED], Mr. Bean did not incur any responsibility to pay. (*Id.* ¶¶ 16-17 & Exs. 2g & 3g.)
- [REDACTED], reimbursement was “based upon [provider] charges that were less than the Medicare allowed amount for the drug[s],” and thus were not based on AWP. (*Id.* ¶ 18 & Exs. 2g & 3g.)
- [REDACTED], and which, by definition, are not reimbursed based on the AWP associated with the Subject Drug. Indeed, “it is not [even] possible to determine the [REDACTED].” (*Id.* at ¶¶ 19-22 & Exs. 2g & 3g.)

[REDACTED], Plaintiffs’ bid to have Mr. Bean serve as a class representative must fail for either of two reasons:

- Despite extensive discovery, Plaintiffs have failed to establish that [REDACTED] marketed by defendant Amgen for use in [REDACTED] based on descriptions included in Mr. Bean’s EOMBs and provider billing statement, but analysis of the individual J-Codes used by Mr. Bean’s providers in seeking reimbursement for these encounters shows that, [REDACTED], Mr. Bean [REDACTED] uses by a company which is not a Track 2 Defendant. (*See* Young Bean Dec. ¶¶ 8-9.) Mr. Bean confirmed this at his deposition. [REDACTED] (Bean Tr. at 66.) And he further testified that [REDACTED]. (*Id.* at 67-69.) Plaintiffs thus have not shown that Mr. Bean even received – much less paid based on AWP for – [REDACTED]
- Even if Mr. Bean had received [REDACTED], any reimbursement for that product was based not on [REDACTED] AWP because his providers billed it under a J-Code ([REDACTED])

██████████) whose rate was determined based on the AWP or ASP of ██████████.<sup>2</sup> By extension, any co-payment by Mr. Bean was similarly based on the AWP for ██████████. And although Plaintiffs have previously argued that they need not show a Plaintiffs' co-payment was based on the AWP for a particular Defendant's product, the argument falls short here because: (1) Mr. Bean cannot establish reliance or causation without establishing that the supposedly false statement upon which he allegedly relied was made by Amgen, and (2) Plaintiffs' proposed class definition, in fact, requires the payment be made (or obligation to pay incurred) based on the AWP for a particular manufacturer's drug.

Accordingly, Mr. Bean neither paid nor incurred any obligation to pay for a Track 2

Subject Drug based on the AWP associated with the drug, within the definition of Class 1. (*Id.*

¶ 23.) He therefore lacks standing to represent Class 1 against any Track 2 Defendant.

**II. THE COMPLEX AND PAPER-INTENSIVE INQUIRY REQUIRED TO DETERMINE THAT NONE OF MR. BEAN'S SUBJECT DRUG ENCOUNTERS FOR TRACK 2 FALLS WITHIN THE DEFINITION OF CLASS 1 CONFIRMS THE INAPPROPRIATENESS OF CLASS TREATMENT FOR PROPOSED CLASS 1.**

Moreover, as expert Young's work with respect to Mr. Bean illustrates, the very process involved in examining whether Mr. Bean's drug transactions fall within the scope of Class 1 highlights why class treatment here is not appropriate. (Young Bean Decl. ¶ 6.) The analysis

required a detailed review of documentation for each encounter, including the Explanation of Medicare Benefits ("EOMB"), the Explanation of Benefits ("EOB") for Mr. Bean's supplemental insurance, supplemental insurance coverage documentation, provider billings or statements, remittance advice, evidence of the source of any multi-source drugs, and other information. Each of these documents must be analyzed to determine whether a plaintiff, such as Mr. Bean, incurred a responsibility to pay for [a] drug encounter based on the AWP for the Subject Drug.

---

<sup>2</sup> For 2004, *see* 69 Fed. Reg. 1084, 1087, 1089, 1266 (Jan. 7, 2004). Reimbursement for administrations in 2005 were based on ASP and not AWP.

(*Id.*) “Indeed, a review of Mr. Bean’s drug encounters illustrates that even when an EOMB, EOB and evidence of payment are available, a review of all appropriate documentation may establish that, as in Mr. Bean’s case, the encounter does not meet the class definition.”<sup>3</sup> (*Id.*)

The sheer complexity of performing this simple threshold step, determining whether one or more of a particular Plaintiff’s drug encounters fall within the Class 1 definition, renders class treatment here all the more inappropriate. After all, if scores of Plaintiffs’ lawyers steeped in knowledge of AWP and drug pricing thought that Mr. Bean’s encounters met the class definition (and none does), how can this Court be expected to sort out millions of class members to determine whether they also meet the class definition? *See Crosby v. SSA*, 796 F.2d 576, 580 (1st Cir. 1986) (when class members are “impossible to identify prior to individualized fact-finding and litigation, the class fails to satisfy one of the basic requirements for a class action”).

### **III. MR. BEAN’S [REDACTED], AND [REDACTED]-LAW BASED CLAIMS, ALSO RENDER HIM INAPPROPRIATE TO REPRESENT CLASS 1.**

#### **A. Texas Law Requires A Showing Of Reliance, Rendering Mr. Bean An Inappropriate Class 1 Representative.**

[REDACTED]. (Bean Tr. at 12-13.) [REDACTED]  
[REDACTED]. To state a claim under the TCPA, Mr. Bean must show – among other things – that he *relied* on an allegedly false AWP. *See, e.g., McLaughlin v. Northstar Drilling Techs., Inc.*, 138 S.W.3d 24, 30 (Tex. Ct. App. 2004) (holding that in order “for a consumer to maintain an action for [violation of Texas’s CPA], the consumer must show that the misrepresentation was a producing cause of his or her damages and that the

---

<sup>3</sup> This is exactly the type of analysis that had to be undertaken with respect to Mr. Bean’s alleged [REDACTED]. Although Plaintiffs contend [REDACTED], citing Bean’s EOMBs and provider billing statements, extensive research of the individual J-Codes at issue showed that the provider billed for these administrations under the [REDACTED] typically used to bill for [REDACTED] – and indeed, Mr. Bean’s deposition confirmed that he most likely received [REDACTED]. (Bean Tr. at 67-69.) This example illustrates the extensive, drug-by-drug research that would be required for each drug encounter for each class member should this Court decide to certify Class 1 in Track 2.

consumer *relied on the misrepresentation to his or her detriment.*") (emphasis added); *see also Henry Schein, Inc. v. Stromboe*, 102 S.W.3d 675, 693 (Tex. 2002) (stating that reliance is an element of Texas CPA's various violations).

Mr. Bean cannot prove such reliance. At his deposition, he expressly disclaimed any reliance on any statements made by Defendants. (Bean Tr. at 62 ("Q. To your knowledge, in paying for any medications that you paid for, have you relied on anything or any representation or any statement from any of the defendants in this case in making the payment? A. No.").)

Indeed, Mr. Bean forthrightly admitted that he was unaware of the term AWP, or what it meant, until his attorneys in this case explained it to him. (*Id.* at 38.) Nor did he know the AWP for any of the medications he used. (*Id.* at 38-39.)<sup>4</sup>

It is for just this reason that courts routinely hold, where a named plaintiff's fraud claims require individual proof of "reliance," that the plaintiff's claims are not "typical" – and that class treatment of the claims is inappropriate. *Patterson v. Mobil Oil Corp.*, 241 F.3d 417, 419 (5th

---

<sup>4</sup> Plaintiffs admit, as they must, that reliance is an element of the Texas CPA for so-called "laundry-list" claims, under Tex. Bus. & Com. Code Ann. § 17.50(a)(1)(A)-(B); they dispute, however, that reliance is an element of the Texas CPA for so-called "unconscionable action" claims, under Tex. Bus. & Com. Code Ann. § 17.50(a)(3). (*See* Docket No. 2889 at 51 n.70.) Plaintiffs apparently have waived any "laundry-list" claim, preferring instead to assume the burden of showing an "unconscionable action." But even that will not help them. Regardless whether reliance is required for § 17.50(a)(2) claims, causation (discussed below) *is* required for such claims – that is, any "unconscionable act" of a Defendant must be the "producing cause" of Plaintiffs' injuries. *See, e.g., Galveston County Fair & Rodeo, Inc. v. Kauffman*, 910 S.W.2d 129, 138 (Tex. App. 1995) (Section 17.50(a)(3) "creates a cause of action where an unconscionable action or course of action is a producing cause of actual damages."). Having failed to rely on Defendants' statements, Mr. Bean cannot show that they were a "producing cause" of his alleged injury. *See, e.g., Jones v. Ray Ins. Agency*, 59 S.W.3d 739, 750 (Tex. App. 2001) ("[M]isrepresentations, appellant's reliance thereon and appellant's resulting damages are some proof of appellant's causes of action under [both a "laundry-list" claim"] and under § 17.50(a)(3) for unconscionable action"); *see also Head v. Finley*, 2004 WL 1699895, at \*6 (Tex. App. 2004) (dismissing both "laundry-list" and "unconscionable action" claims: "[F]or the same reasons that support our conclusion that Appellant's claims requiring proof of reliance [on the Sellers' Disclosure] must fail, we conclude that there is no evidence that the Sellers' Disclosure was the producing cause of Appellant's alleged damages. Consequently, Appellant's claim under section 17.50(a)(3) also fails.") (not designated for publication). Indeed, Texas courts have refused to certify classes asserting "unconscionable act" claims under § 17.50(A)(3) because, as with reliance, those claims require individualized proof as to what the consumer would have done but for the misrepresentation. *See Wall v. Parkway Chevrolet, Inc.*, 176 S.W.3d 98, 105 (Tex. App. 2004) (holding that an individualized inquiry into each buyer's circumstances is required to answer the question whether the misrepresentation of a fee on a purchase invoice was unconscionable); *Peltier Enters., Inc. v. Hilton*, 51 S.W.3d 616, 623-24 (Tex. App. 2000) (holding that an individualized inquiry is required into what each consumer could have or would have done if he had known that the dealer was making money on the difference between the interest rate the consumer was paying and the bank was charging).



Cir. 2001) (“Claims for money damages in which individual reliance is an element are poor candidates for class treatment, at best. We have made that plain.”); *Mowbray v. Waste Mgmt. Holdings, Inc.*, 189 F.R.D. 194, 198 (D. Mass. 1999), *aff’d on other grounds*, 208 F.3d 288 (1st Cir. 2000); *see also Gariety v. Grant Thornton, LLP*, 368 F. 3d 356, 362 (4th Cir. 2004) (“[B]ecause proof of reliance is generally individualized to each plaintiff allegedly defrauded, fraud . . . claims are not readily susceptible to class action treatment[.]”); *Sandwich Chef of Texas, Inc. v. Reliance Nat’l Indem. Ins. Co.*, 319 F. 3d 205, 219 (5th Cir. 2003) (noting that the need to prove reliance creates “a working presumption against certification”); *Stout v. Byrider*, 228 F.3d 709, 718 (6th Cir. 2000) (holding typicality and predominance requirements not met where factual core of case, including fraud claim, was whether each person relied upon false representations or failures to disclose in disputed transactions and, if so, what damages were proximately caused by that reliance); Track 1 Summary Judgment Hearing in *In re Pharm. Indust. Average Wholesale Price Litig.* At 51-52 (“THE COURT: . . . And the reliance question, if we get there, I mean, in other words, actual reliance is not going to happen with any of these classes. That’s no part of this case, if there’s a requirement of actual reliance like in some of those advertising cases. So we need to figure out from the get-go which cases just to carve off.”). The result here should be no different: Mr. Bean’s statutory need to demonstrate reliance renders him inappropriate to represent Class 1.

**B. Texas Law Requires A Showing Of Causation, Which Further Renders Mr. Bean Inadequate.**

Mr. Bean must also prove, under the TCPA, that a Track 2 Defendant’s alleged misrepresentations were the “producing cause” of his damages. *See* Tex. Bus. & Comm. Code Ann. § 17.50(a) (Vernon 2005); *McLaughlin*, 138 S.W.2d at 30. To do so, Mr. Bean must show that any misrepresentation was both a “cause-in-fact” and a “substantial factor” in bringing about

his injuries. *See Brown v. Bank of Galveston, Nat'l Ass'n*, 963 S.W.2d 511, 514 (Tex. 1998) (citing *Union Pump Co. v. Allbritton*, 898 S.W.2d 773, 775 (Tex. 1995)).

Again, Mr. Bean cannot make such a showing. He testified that he never decided to take (or not take) a drug based on the AWP of the drug. (Bean Tr. at 39.) Nor did Mr. Bean indicate that any alleged inflation of AWP's caused him to pay his providers more than he expected. To the contrary, he testified that he believed his doctors formulated his treatment plan based on what was best for him rather than how much money the doctors would make; that he did not know how much it costs doctors to purchase, administer, or store his medications; and that he did not feel the doctors had any obligation to tell him "what they were paying for drugs and what they might be reimbursed for those drugs." (*Id.* at 61-62.)

As with reliance, courts routinely hold that where a named plaintiff's claims require proof of causation, class treatment of those claims is not appropriate. *See, e.g., Poulos v. Caesars World, Inc.*, 379 F.3d 654, 664-666 (9th Cir. 2004); *Markarian v. Connecticut Mut. Life Ins. Co.*, 202 F.R.D. 60, 69 (D. Mass. 2001) (refusing to certify class because individual issues of causation dominated because the "question of causation must be decided with regard to each purchaser in the context of the particular information" the purchaser had); *see generally Lester v. Perducani*, 217 F.R.D. 345, 352 (M.D. Pa. 2003) (explaining that "[a]lthough several courts have noted that variations in the *amount* of damages do not preclude certification, this conclusion does not obviate the need for plaintiffs to establish the *fact* of damages when class-wide injury cannot be presumed and forms and essential element of their case. . . . That [plaintiffs and class members] were allegedly defrauded in a similar manner does not establish common injury."). (emphases added). Again, the result here should be no different: Mr. Bean's statutory need to demonstrate causation renders him inappropriate to represent Class 1.

**CONCLUSION**

For the foregoing reasons, in addition to those set out in the Track 2 Class Certification Opposition Brief and the various individual Defendants' briefs, Plaintiffs' motion to certify Track 2 Classes 1, 2, and 3 as against the Track 2 Defendants should be denied.

Dated: August 25, 2006

Respectfully submitted,

/s/ Brian J. Murray

James R. Daly

Tina M. Tabacchi

Brian J. Murray

JONES DAY

77 West Wacker Drive, Suite 3500

Chicago, Illinois 60601

Telephone: (312) 782-3939

Facsimile: (312) 782-8585

*Counsel for Defendant Abbott Laboratories, Inc.,  
and on behalf of the Track 2 Defendants.*

**CERTIFICATE OF SERVICE**

I, Brian J. Murray, an attorney, hereby certify that I caused a true and correct copy of the foregoing TRACK 2 DEFENDANTS' MEMORANDUM REGARDING HAROLD BEAN, IN FURTHER OPPOSITION TO CLASS CERTIFICATION, and supporting Supplemental Expert Declaration of Steven J. Young In Support Of The Track 2 Defendants' Opposition To Class Certification, to be served, via Fed Ex, upon:

Thomas M. Sobol  
HAGENS BERMAN SOBOL SHAPIRO LLP  
One Main Street, 4th Floor  
Cambridge, MA 02142  
*Plaintiffs' Liason Counsel*

This 25th day of August, 2006.

/s/ Brian J. Murray  
Brian J. Murray